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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,104	02/10/2005	Birkir Sveinsson	3535-0138PUS1	3834
2292 7590 06/23/2008 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
EXAMINER				
WEN, SHARON X				
ART UNIT		PAPER NUMBER		
1644				
NOTIFICATION DATE		DELIVERY MODE		
06/23/2008		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary

Application No.

10/524,104

Applicant(s)

SVEINSSON, BIRKIR

Examiner

SHARON WEN

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5 and 15-22 is/are pending in the application.
- 4a) Of the above claim(s) 16 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 15 and 17-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's amendment, filed 02/29/2008, has been entered.

Claims 4 and 6-14 has been canceled.

Claims 15-22 have been added.

Claims 1-3, 5 and 15-22 are pending.

Newly submitted claims 16 and 22 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons.

The newly submitted claim 22 is drawn to a method of treating psoriasis comprising administering a CGRP antagonist wherein the CGRP antagonist encompasses compounds previously not claimed. Claim 22 is drawn to different and distinct CGRP antagonists from the ones disclosed in previously presented claims with respect to their physicochemical properties and/or mode of action; and they do not share a common structure that is disclosed to be essential for common utility.

In addition, the newly submitted claim 16 is drawn to a distinct route of administration, i.e., subcutaneous infusion via microdialysis, which is distinct from topical route of administration with respect to one or more ingredients, method steps, and/or endpoints as the elected species of routes of administration.

Since Applicant has received an action on the merits for the originally elected and/or presented invention, this invention has been constructively elected by original presentation for prosecution on the merits.

Accordingly, claims 16 and 22 is withdrawn from consideration as being directed to a non-elected invention (e.g, species). See 37 CFR § 1.142(b) and MPEP § 821.03.

Claims 1-3, 5 and 15, 17-21 are currently under examination as they read on a method of treating or remedying psoriasis comprising administering a CGRP antagonist as it reads on CGRP 8-37 as the elected invention.

2. This Action will be in response to Applicant's Arguments/Remarks, filed 02/29/2008.

The rejections of record can be found in the previous Office Action.

Priority

3. The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed applications, PCT/IS03/00023 and Icelandic application, 6496 fail to provide sufficient written support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. In particular, the priority applications do not appear to have written support for the newly added claims 17 and 21 in the recitation of:

"a polypeptide of amino acids **27-37** of SEQ ID NO: 1",

"a polypeptide of amino acids **28-37** of SEQ ID NO: 1" and

"a polypeptide of amino acids **30-37** of SEQ ID NO: 1" .

The newly added limitations mentioned above, in Applicant's amendment, filed 02/29/2008, were not clearly disclosed in the instant applications and would have changed the scope of the application as-filed.

For a more complete discussion, see the rejection under 35 USC 112, first paragraph, Written Description / New Matter.

Should Applicant disagree with the Examiner's factual determination above, it is incumbent upon Applicant to provide a showing that specifically supports the instant claim limitations.

Sequence Compliance

4. Applicant's newly submitted Substitute Sequence Listing comprising the amino acid sequence set forth in SEQ ID NO: 1 is acknowledged.

However, it appears that SEQ ID NO: 1 has only 36 amino acids which appears to be inconsistent with the claim recitation of "amino acids 8-37 of SEQ ID NO: 1". Therefore, the following rejection is set forth under 35 USC 112 second paragraph.

Claim Rejections - 35 USC § 112 second paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 2, 17-19 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 2, 17-19 and 21, the following phrases:

"a polypeptide of amino acids 8-37 of SEQ ID NO: 1",

"a polypeptide of amino acids 27-37 of SEQ ID NO: 1",

"a polypeptide of amino acids 28-37 of SEQ ID NO: 1" and

"a polypeptide of amino acids 30-37 of SEQ ID NO: 1"

render the claims indefinite because SEQ ID NO: 1 has only 36 amino acids.

Therefore, the metes and bounds of the claimed polypeptides are ambiguous and ill-defined. For example, it is unclear to one of skill in the art whether the 36th residue of SEQ ID NO: 1 is the 36th or the 37th amino acid encompasses in the above mentioned claim limitations. As such, the claims are rendered indefinite.

7. The previous rejection under 35 USC 112 second paragraph for the recitation of "including" and "such as" has been withdrawn in view of Applicant's amendment, filed 02/29/2008

Claim Rejections - 35 USC § 112 first paragraph

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 2, 17 and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the **written description** requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

*The following is a **Written Description / New Matter** rejection.*

Applicant's amendment, filed 02/29/2008, contains new matter that has been added with the newly added claim. However, the specification as-filed, does not provide sufficient written description for the following limitations drawn to the new amino acid ranges of the CGRP polypeptide fragments:

- "a polypeptide of amino acids **27-37** of SEQ ID NO: 1",
- "a polypeptide of amino acids **28-37** of SEQ ID NO: 1" and
- "a polypeptide of amino acids **30-37** of SEQ ID NO: 1".

Upon reviewing of the application as-filed, the written support of the newly added limitations mentioned above is not readily apparent.

The specification as-filed does not provide written description or set forth the metes and bounds of the above-mentioned limitation. The specification does not provide sufficient landmarks nor direction for the CGRP antagonist encompassing the above-mentioned limitation as they are currently recited. The instant claims now recite limitations which were not clearly disclosed in the specification as-filed, and now change the scope of the instant disclosure as-filed. Such limitation recited in the present claims, which did not appear in the specification, as-filed, introduce new concept and violate the description requirement of the first paragraph of 35 U.S.C. 112.

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Applicant is required to cancel the new matter in the response to this Office Action.

Alternatively, Applicant is invited to provide sufficient written support for the limitations indicated above. See MPEP 714.02 and 2163.06.

Applicant's amendment, filed 02/29/2008, necessitated the new grounds of rejection herein.

10. The previous written description rejection under 35 USC 112 first paragraph for the recitation of "CGRP derivatives" has been withdrawn in view of Applicant's amendment, filed 02/29/2008.

11. The previous enablement rejection under 35 USC 112 first paragraph for the recitation of "preventing psoriasis" has been withdrawn in view of Applicant's amendment, filed 02/29/2008.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1-3, 5, 15 and 17-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Brenton ET al. (U.S. Patent 6,019,967, see entire document).

Applicant's arguments, filed 02/29/2008, have been fully considered but have not been found convincing essentially for the reasons of record.

Given that Brenton et al. teach a method of treating psoriasis comprising administering topically or dermally CGRP 8-37 (e.g., see Abstract and column 4, in particular, line 44), the prior art anticipates the present claims. Furthermore, given that the prior art teaches the same or nearly the same CGRP 8-37, it would inherently "lack wildtype CGRP activity and binds to CGRP receptor" because the limitation is a mere inherent property of the CGRP antagonist.

In response to Applicant's argument that the prior art lacks enablement, it is noted that "the standard for enablement of a prior art reference for purposes of anticipation under section 102 differs from the enablement standard under 35 USC § 112" and that "anticipation does not require actual performance of suggestions in a disclosure. Rather, anticipation only requires that those suggestions be enabled to one of skill in the art." (See, *Impax Laboratories Inc.*, 81 U.S.P.Q.2d 1001, 1012, citing *Novo Nordisk Pharms., Inc v. Bio-Tech. Gen. Corp.*, 424 F.3d 1347, 1355 (Fed. Cir. 2005)).

Furthermore, Applicant has not provided any deficiency in the prior art teaching.

Attorney argument cannot take the place of the evidence lacking in the record. *Meitzner v. Mindick*, 193 USPQ 17, 22 (CCPA 1977).

Applicant's arguments have not been persuasive.

Therefore, the rejection of record is **maintained** for the reasons of record as it applies to amended and newly added claims. The rejection of record is incorporated by reference herein, as if reiterated in full.

Conclusion

14. No claim is allowed.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHARON WEN whose telephone number is (571)270-3064. The examiner can normally be reached on Monday-Thursday, 8:30AM-6:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on (571)272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sharon Wen, Ph.D./

Examiner, Art Unit 1644

June 18, 2008

/Phillip Gambel/

Phillip Gambel, Ph.D., J.D.

Primary Examiner

Art Unit 1644

Technology Center 1600

June 18, 2008